REMARKS

Claims are all the claims pending in the application.

I. Response to Claim Objections

Claim 9 is objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. The Examiner states that claim 9 recites the limitation that pirfenidone comprises 1-25% weight of the composition, whereas independent claim 1 recites that pirfenidone comprises about 10% to about 25% of the composition. Therefore, the Examiner considers that claim 9 fails to further limit the amount of pirfenidone in the composition.

Claim 9 is amended to recite that pirfenidone comprises 10-25% by weight of the composition, thereby obviating the objection.

Accordingly, Applicants respectfully request withdrawal of the objection.

II. Response to Claim Rejections under 35 U.S.C. § 102

Claims 1-2 and 5-8 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Scheiwe et al (US 6,492,395).

Applicants traverse the rejection.

Claim 1 is amended to recite that pirfenidone comprises 10 to 25% by weight of the composition as amended.

Scheiwe et al discloses a pharmaceutically acceptable topical formulation for the treatment and/or prevention of skin ailments comprising pirfenidone with an excipient, characterized in that the excipient comprises one or more plasticizers, one or more antioxidants,

one or more gel-forming agents and a sufficient pH adjusting agent for bringing the pH of the formulation to a value from 4 to 8. Abstract.

Scheiwe et al discloses that the amount of the active ingredient, i.e., pirfenidone, is preferably within the range of about 0.5% to about 9% by weight, preferably from about 3% to about 7% by weight of the entire composition. Column 2, lines 31-37. Thus, the range taught by Scheiwe et al is not within the presently claimed range and therefore does not constitute anticipation within the meaning of §102. Anticipation under §102 can be found only when the reference discloses exactly what is claimed. A reference which teaches a value or range that is close to, but does not overlap or touch, the claimed range does not anticipate the claimed range. See MPEP § 2131.03(III). In this case, the reference does not disclose an example wherein the active ingredient of the composition, i.e., pirfenidone, is employed in an amount of 10% to about 25%. To the contrary, the Scheiwe et al discloses that typical formulation and preferred formulations contain 3 to 7 wt% of the active ingredient, which is not close to the recited range of "10% to about 25%". Thus, for at least these reasons, Scheiwe et al does not anticipate the presently claimed invention.

Accordingly, Applicants respectfully request withdrawal of the §102 rejection.

III. Response to Claim Rejections under 35 U.S.C. § 103

A. Margolin

Claims 1-2 and 8 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Margolin (WO 94/26249).

Applicants respectfully traverse the rejection.

Margolin only has a listing of theoretical uses and does not describe nor specify any coposition of the formulations of the various dosage forms suggested theoretically for the use of pirfenidone. The term "composition" used in the examples and claims is misleading as the word "composition" should describes and specifies "components" of a formulation and not just name the "dosage forms" theoretically. In pharmaceutical terminology the so-called "compositions" (such as tablets, capsules, etc.) named in the description of Margolin are termed "dosage forms" (and not compositions). Compositions always have to detail the "components" of a dosage form, which is nowhere given in Margolin. Hence, Margolin does not teach or suggest the presently claimed invention.

The Examiner admits that Margolin does not disclose a solvent and asserts that because the compositions may be formulated as injections, a solvent must be present. However, the Examiner's position assumes that all injections are solutions, which is not the case. The fact is that Margolin is silent about a solvent and there is no reasonable technical basis for asserting that a solvent capable of dissolving pirfenidone in a concentration of about 10% to about 25% by weight is "necessarily" present.

For example, several poorly water soluble drugs which cannot be dissolved in water (the most commonly used solvent for injections), such drugs are given as "injectable suspensions of this drug in water. A typical example is that of the anti-rheumatic drug, "Cortisone". The USP and BP contain monographs for "Sterile Cortisone Acetate suspensions" which are injected intramuscularly. Even injections of emulsions are given, such as for parenteral nutrition purposes containing fat-soluble vitamins, such as Vitamin A, E and K.

Additionally, Margolin does not disclose a liquid composition comprising pirfenidone in amount within the presently claimed range. Margolin discloses an ointment comprising 5 to 10% pirfenidone and does not teach or suggest making a liquid composition using a solvent as recited in the present claims. Thus, there is motivation for one of ordinary skill in the art to modify the disclosure of Margolin and make a liquid composition comprising pirfenidone and a solvent capable of dissolving pirfenidone in a concentration of about 10% to about 25 % as presently claimed.

B. Scheiwe in view of Iyer et al

Claims 3-4 and 9-11 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Scheiwe et al (US 6,492,395) in view of Iyer et al (US 2004/0033257).

Applicants respectfully traverse the rejection.

Scheiwe et al does not identically disclose all elements of the present invention for the reasons set forth above. Specifically, Scheiwe describes a formulation of oil-in-water emulsion-cream containing pirfenidone on an amount of 3% to 7% by weight of said composition, but preferably in the range of about 0.5% to about 9% by weight. Hence, Scheiwe does not disclose, teach or suggest pirfenidone in a concentration of 10% to about 25%" and Iyer et al does not remedy this deficiency.

Iyer et al does not disclose, teach or suggest a liquid composition comprising pirfenidone. Iyer et al teaches gelatin capsules comprising loratidine. Iyer et al specifically describes a formulation of loratidine, solubilized in a mixture of solvent and emulsifiers and which is specifically to be used in making soft gelatin capsules of this particular drug. The maximum concentration of the drug (as shown in Table 1 at paragraph [0030]) reached in the solvent

mixture is 8% drug. The use of Transcutol P alone as a solvent is not specified, and it is only one component along with a mixture of other components of the formulation (for making soft gelatin capsules of loratidine). Hence, Iyer et al does not teach or suggest the presently claimed invention and does not remedythe deficiencies of Scheiwe.

Thus, one of ordinary skill in the art would not have been motivated to combine the references with a reasonable expectation of success.

Accordingly, Applicants respectfully request withdrawal of the rejection.

C. Margolin et al in view of Iyer et al

Claims 3-4 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Margolin (WO 94/262249) in view of Iyer et al (U. S. 2004/0033257).

Applicants respectfully traverse the rejection.

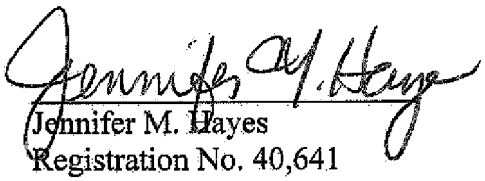
There is no motivation to combine the references as suggested by the Examiner. Specifically, Margolin teaches topical dosage forms comprising pirfenidone and Iyer et al teaches gelatin capsules comprising loratidine. In particular, the main indication for pirfenidone is focused on the treatment of fibrosis of the lungs, and the present invention enables the drug solution to be inhaled as fine droplets from a nebulizer device. The pharmacological advantages of pulmonary absorption are the almos instatntaneous absorption of the drug into the blood, avoidance of hepatic first-pass loss, and, in case of pulmonary disease, local application of the drug at the desired site of action. Thus, one of ordinary skill in the art would not have been motivated to combine the references with a reasonable expectation of success. Even if the references were combined, the present invention which is directed to a liquid composition would not have been achieved.

IV. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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